

SPL R4 Common Technical Errors eBook

Interpretations & Solutions for
Technical Errors in SPL R4 Documents
Submitted to FDA

Version 1.0

Purpose:

This SPL R4 training eBook is to be utilized by SPL document authors as a reference to determine the source of **common** errors in SPL documents submitted to FDA. This is a “living” document. More content will be included as SPL R4 validation procedures are added or refined. Eventually, this eBook will contain an interpretation of every possible technical error which can occur in an SPL R4 document

How to use this eBook

To eliminate some instances of duplicative error message interpretations in this eBook, this document has been organized into sections by subject. Therefore, if you have several types of errors in your submission, in some cases, you may have to refer to different sections of this eBook. For example, document tracking information is to be included in all three SPL R4 types so the error message interpretations relating to document tracking errors have been grouped into a section labeled “Document Tracking Information.” The other errors in your document may be found in another section (e.g. NDC Labeler Code.) However, a few of the error interpretations are repeated in the appropriate sections. The following table has a list of this eBook’s sections that are applicable to each SPL R4 document type:

SPL R4 Document Types		
NDC Labeler Code	Establishment Registration	Content of Labeling/Listing
Document Tracking Information	Document Tracking Information	Document Tracking Information
NDC Labeler Code	Establishment Registration	Content of Labeling (CoL)/Listing
Contact & Address Information	Contact & Address Information	Images
SPL Schema	SPL Schema	SPL Schema
Packaging & Submitting the SPL	Packaging & Submitting the SPL	Packaging & Submitting the SPL

How do you know when you have received an error message?

A second or third acknowledgment indicates that there is an error in your submission. At the time of the publication of this eBook, error messages (second or third acknowledgments) are transmitted within 24 – 48 hours of FDA's receipt of your submission.

Downloading and viewing an error message

If you have received a second or third acknowledgment, you should download the error message for review. For instructions on downloading and viewing SPL R4 error messages transmitted via the FDA OC Gateway, we recommend that you review the SPL training eBook # 10 via this web page: <http://spl-work-group.wikispaces.com/SPL+eBooks++Graphic+Guides>.

Configuring your PC to view an error message

If you are experiencing technical difficulties resulting in your inability to view the error message you have downloaded, we recommend that you follow these steps:

(for Internet Explorer 7.0)

Click the "Tools" menu and select "Internet Options".

Click the "Security" tab.

Click the "Custom level" button.

Scroll down to the "Miscellaneous" section.

Enable the "Access data sources across domains".

Click "OK" to accept the update.

Click "OK" to close the security dialog.

Validating SPL documents prior to submission to FDA

The Pragmatic Validator Lite Tool is a great resource to utilize to detect technical errors in your SPL R4 documents. However, the validator is **NOT** connected to the FDA database and therefore will **NOT** detect **ALL** SPL R4 technical errors. The validator tool is accessible via this hyperlink: <http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>.

Need Additional Assistance w/Error Message Interpretation?

If, after you have reviewed the SPL step-by-step instructions, SPL training eBooks (including this eBook), and eCards, you still require additional assistance regarding the interpretation of your error message, you may request help with the interpretation of the error by submitting an e-mail with the core ID of the submission associated with the error message to spl@fda.hhs.gov. Ensure that you are sending the core ID and not the message ID or submission ID. For assistance with locating the core ID, see SPL training eBook # 10 on this web page: <http://spl-work-group.wikispaces.com/SPL+eBooks+--+Graphic+Guides>.

Other SPL training eBooks

There are other SPL R4 training eBooks and eCards that are accessible via this hyperlink: <http://spl-work-group.wikispaces.com/SPL+eBooks+--+Graphic+Guides>.

Document Tracking Information	
The document tracking information is the: document root ID, setID, version number, and document's effective time.	
Error Message	Solution
SPL file name must be the id root followed by ".xml"	Name the file with the document root ID. (Do not use creative names for the file name.) Include “.xml” after the document root ID
There must be an effective time with at least the precision of day in the format YYYYMMDD	Enter the date in the document's effective time field using the YYYYMMDD format (e.g. Enter 20091221 for December 21, 2009)
Value " is not facet-valid with respect to pattern '[0-9]{1,8} ([0-9]{9,14} [0-9]{14,14})\.[0-9]+)([+ -][0-9]{1,4})?' for type 'ts'.	Enter the date in the document's effective time field using the YYYYMMDD format (e.g. Enter 20091221 for December 21, 2009)
The value " of attribute 'value' on element 'effectiveTime' is not valid with respect to its type, 'ts'.	Enter the date in the document's effective time field using the YYYYMMDD format (e.g. Enter 20091221 for December 21, 2009)
id must be unique across all documents	Change the document root ID (GUID) to a GUID that is not in FDA system.
" is not a valid value of union type 'uid'.	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in ID field.
The value " of attribute 'root' on element 'id' is not valid with respect to its type, 'uid'.	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in ID field.
id root must be a Globally Unique Identifier (GUID).	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in (document) ID field.
setId must be a GUID	Generate a setId using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setId field.
The value " of attribute 'root' on element 'setId' is not valid with respect to its type, 'uid'.	Generate a setId using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setId field.

Document Tracking Information	
The document tracking information is the: document root ID, setID, version number, and document's effective time.	
Error Message	Solution
Value of version number must be a whole number > 0	Enter a version number which is a whole number that is greater than "0"
" is not a valid value for 'integer'.	Use a whole number in the version number field.
The value " of attribute 'value' on element 'versionNumber' is not valid with respect to its type, 'int'.	Use a whole number in the version number field.
Value of version number must be greater than the value of any previously submitted version for the same setId	Increase the document version number by one whole number.

NDC Labeler Code SPL Documents	
Determine the source of the errors in one's NDC Labeler Code SPL document in the list below.	
Error Message	Solution
There must be two ids (except for an initial labeler code request, which must be submitted with only one id.)	<p>Include your 4- or 5-digit labeler code unless you are requesting a labeler code. Delete the NDC Labeler code field if you do not have a labeler code to enter. If you receive this message from the Pragmatic Data Validator Lite tool, then note that the error includes this statement: "except for an initial labeler code request, which must be submitted with only one id."</p> <p>In this instance, the "id" is the labeler code. (The second "id" is the DUNS Number. The DUNS Number should only be included in the DUNS Number field.)</p>
One id must have the root 2.16.840.1.113883.6.69 and an extension (except for an initial labeler code request, which must be submitted without this id)	<p>If you were already assigned an NDC Labeler Code, then enter the NDC labeler code. If this submission is a requests for labeler code assignment, then delete the NDC Labeler Code field.</p>

NDC Labeler Code SPL Documents	
Determine the source of the errors in one's NDC Labeler Code SPL document in the list below.	
Error Message	Solution
The id with the root 2.16.840.1.113883.6.69 must not be associated with any other document of type "NDC Labeler Code request" with a different setId	Do not submit the same NDC labeler code in a different SPL which has a different setId.
One id has the root 2.16.840.1.113883.6.69 and an extension (except for an initial labeler code request, which should be submitted without this id)	Include the labeler code in the NDC Labeler Code number field unless you are requesting a labeler code. If you are requesting a labeler code then delete the NDC Labeler Code field.
The id extension with the root 2.16.840.1.113883.6.69 has 4 or 5 digits	Enter an already assigned labeler code using 4 or 5 digits . Do not include leading zeros that are not included in the labeler code segment of your 10-digit NDC
One id must have the root 1.3.6.1.4.1.519.1 with a 9-digit extension	The "id" in this instance is the DUNS Number. Enter the DUNS Number in this field. DO NOT include hyphens in the DUNS Number. Ensure that no spaces are entered (with the keyboard space bar) before or after DUNS Number.

Establishment Registration SPL	
Error Message	Solution
has one or two id elements	In this instance, the "id elements" are the DUNS Number and FEI number Enter DUNS Number (FEI number may not be assigned yet. If FEI number for establishment has been assigned, enter it in the FEI number field.)
One id has the root 1.3.6.1.4.1.519.1	Enter 9-digit DUNS Number (without hyphens)

Establishment Registration SPL	
Error Message	Solution
The id with the root 1.3.6.1.4.1.519.1 has a 9-digit extension	Enter 9-digit DUNS Number (without hyphens)
id must not be associated with any other set id for document type “Establishment registration”	DUNS Number for registrant is associated with only one Establishment Registration SPL’s setID. Include all of the drug establishments owned/operated by registrant in one Establishment Registration SPL document. If you have already submitted to FDA an SPL as a test or official submission, use the setID of that original Establishment Registration SPL document.
The id is not associated with another establishment in the same SPL file.	The same DUNS Number is used more than once in your file. DUNS Numbers are site-specific Obtain the other location’s DUNS Number from D&B. If D&B will only assign one DUNS Number because the sites are located on the same campus , at the time of the publication of this eBook, you should enter information for one of the drug establishments.
The id with the root 1.3.6.1.4.1.519.1 along with the establishment postal code (if any) and country must match the DUNS number, postal code and country in the Dun and Bradstreet database	Ensure that the DUNS Number and address for a drug establishment is correct . Check to be sure that you have added the ISO 3166-1 3-letter country code. Remove any spaces created with keyboard space bar which are located directly before or after country code.
If there is a second id element, then its root is 2.16.840.1.113883.4.82 and the extension is 7 or 10 digits	In this instance, the “id element” is the FEI number. If you have an FEI number enter it. If not, delete the FEI number field. Enter SEVEN- or TEN- digit FEI numbers. If necessary, include leading zeros for older FEI numbers (e.g. 0001444)
The code comes from the business operations list except for C73599 (import) and C73330 (united states agent)	Add a type of operation; however, DO NOT add “import” or “united states agent” as a type of operation for an establishment. Include “import” or “united states agent” in the Importer or United States Agent fields – NOT as the type of operation for a drug establishment

Establishment Registration SPL	
Error Message	Solution
There are one or more establishment operation details (performance act definitions).	Include one or more types of operation for each drug establishment
If the country for the establishment is not “USA”, then there is one US agent	Foreign drug establishment should include information (US agent’s company name, DUNS Number, telephone number, and e-mail address) for one US agent.
If the country code for the establishment is not USA, then there may be one or more import businesses.	Foreign drug establishment which export drugs to US should include importer information (importer’s company name, DUNS Number, telephone number and e-mail address)

Contact & Address	
This section includes some of the contact or address errors in NDC Labeler Code and Establishment Registration SPL	
Error Message	Solution
telephone numbers must be global telephone numbers;	Enter a telephone number
telephone numbers must contain no letters or spaces;	Enter the correct format for a telephone number Ensure that there are no spaces created with the keyboard space bar which are located before or after the telephone number.
Must include hyphens to separate the country code, area codes and subscriber number	Use hyphens to separate the country code, area codes and subscriber number
'mailto:' is not a valid value for 'anyURI'.	Enter an e-mail address
an email address is of the simple form <username>@<dns-name>	- Enter a valid e-mail address - Remove spaces located before or after e-mail address that were created with keyboard space bar.
Country must be composed of letters only	Enter a three-letter country code (ISO 3166-1) Delete spaces included before or after country code. Link to 3-letter country code list: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162567.htm

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
The document body contains two or more sections	Include more than one section in your content of labeling/listing (CoL/listing) document
One section contains the product data elements	Include a section with product data elements (drug listing data elements)
There is one labeler	Include the name of the owner of the labeler code.
There is one id	In this instance, reference is made to the labeler's DUNS Number. Should be identical to labeler's DUNS Number that is associated with labeler code (first segment of NDC in this CoL/listing file) submitted in NDC Labeler Code SPL document.
First segment matches an NDC Labeler Code associated with the Labeler id.	Ensure that the labeler code and labeler's DUNS Number is identical to the labeler code and labeler's DUNS Number in your drug listing SPL document.
The setId is not associated with any top level product with a different NDC Labeler Prefix	The labeler code in a previously submitted CoL/listing SPL document which has the same setId of this CoL/listing SPL document should be identical to the labeler code in this CoL/listing SPL document. (Enter one labeler code per CoL/listing SPL) This validation procedure does not apply to the labeler code of the NDC for products which are described as components of a kit (combination package)
If the marketing status code for any of the products is not "completed," then there are one or more establishments.	If there is a product which is still marketed then include the information for one or more drug establishments. If all of the products in this CoL/listing SPL are discontinued then you do not have to include the information for any drug establishment in this CoL/listing file.
The code comes from the business operations list except for C73599 (import) and C73330 (united states agent)	Add a type of operation; however, DO NOT add "import" or "united states agent" as a type of operation for an establishment.

Content of Labeling & Listing SPL Documents

You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
Act definition code matches code for an establishment with same id previously submitted in documents of type “establishment registration”	If the drug establishment included in the establishment data elements section of your CoL/Listing SPL has been electronically registered via an Establishment Registration SPL, the type of operation included for the establishment in your CoL/Listing matches the type of operation in the previously submitted Establishment Registration SPL document.
Product data element section has an id	In this instance, the “id” identifies a section. Include a GUID as the id for the section.
id root is a GUID and has no extension.	In this instance, the “id” identifies a section. Include a GUID as the id for the section.
There is an effective time with at least the precision of day in the format YYYYMMDD	Enter the date in the section’s effective time field using the YYYYMMDD format (e.g. Enter 20091221 for December 21, 2009)
There is one or more product	Describe one or more products in the product data element section.
There is a product code	Enter an NDC Product Code (An NDC Product Code are the first two segments of the 3-segment, 10-digit NDC Package Code)
Code has two segments separated by a hyphen	Insert a hyphen between the NDC Labeler Code (first segment of 3-segment, 10-digit NDC Package Code) and NDC Product Code (second segment of 3-segment, 10-digit NDC Package Code)
Segments follow the pattern of 4-4, 5-4 or 5-3	Follow the pattern assigned if you received a labeler prior to June 1, 2009. Examples of the patterns of an NDC Product Code are: 4-4: 2222-5555, 5-4: 22222-2222, or 5-3: 22222-876) DO NOT use these examples in your SPL document. Use your own labeler code, etc... Labelers with labeler codes assigned after June 1, 2009, can select pattern; however, once pattern is selected and used in an official CoL/Listing SPL submission, it can not be altered.
The first two segments of the NDC Package Code matches the NDC Product Code	The first two segments of the NDC Package Code (3-segment NDC) are identical to the first two segments of the NDC Product Code. (per product data elements table)
Code is not associated with another set id except under parts.	The NDC Package Code (3-segment NDC) may only be associated with one CoL/Listing document’s setID except in the case where the 3-segment NDC is included as a component of a kit (combination package).

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
If the NDC Package Code has been previously submitted, then the package form code and quantity value and unit are the same as in the most recent submission for this NDC code.	The package description associated with the NDC Package Code (3-segment NDC) of the incoming CoL/Listing SPL document should be identical to the package description for this NDC Package Code in the previously submitted CoL/Listing SPL document.
Name contains no special symbols (e.g., no “®” or “™” etc) and no “USP”	Do not include symbols or “USP” in the proprietary name of the products in the product data elements section. NOTE: Do not include the dosage, route or strength in the proprietary name field
Generic medicine name contains no special symbols (e.g., no “®” or “™” etc) and no “USP”	Do not include symbols or “USP” in the generic/established name of the product in the product data elements section. NOTE: Do not include the dosage, route or strength in the generic name field
Remove additional qualifiers (e.g. dosage form, route of administration, etc...) from product names in the product data elements section.	Remove dosage form, route of administration, etc... from the product name(s) in the product data elements section of the SPL document.
Name must match the code	Use the preferred name and UNII in the UNII list. If UNII is not included in UNII list then request UNII via e-mail to spl@fda.hhs.gov
Active moiety name does not include any of the names in the Active moiety validation (counter ion) list except if the word appears by itself optionally followed by “cation” or “anion” or “ion”.	Do not include names in the active moiety counter-ion list (labeled “counter-ion validation” located in the Additional Validation Files located on this web page: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm unless word appears by itself optionally followed by “cation” or “anion” or “ion”.
There is a section with the code 51945-4 (principal display panel) with a jpg file (carton/container label).	Include each representative sample of a carton/container label in a major SPL section with section heading “Package.Label Principal Display Panel. (one carton/contain label image per section)
If the products has parts, then the form code is C47916	If you are describing a combination product then use “kit” as the dosage form.

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
If the NDC Product Code was previously submitted, then the product and generic name, active ingredient UNII, dosage form, active ingredient strength, product characteristics of size, shape, color and imprint code must be the same as in the most recent submission for this NDC code.	<ul style="list-style-type: none"> -The values of the data elements listed in the table cell horizontally adjacent to this cell should match those of the previous SPL for the product(s). - If aforementioned values differ from those in an SPL R3 document then request a “manual override.” - If request is not granted, you will be contacted via e-mail. - If request is granted you will NOT be notified.
If the code is not C73583, C73584, C73585, C73588, C73593, C73594, C73603, C73604, C73605, C75302, C80438, C80440, C80441 or C80442 then there must be no id.	<p>Remove the application or citation number or application and citation number code system for products which do not have application or citation numbers.</p> <p>Delete the empty application or citation number field. You may have to request to have the empty ID element removed if you still receive error after following above steps.</p>
If the marketing category code is not C73626 (bulk ingredient) or C73613 (unapproved medical gas), then there must be at least one other content of labeling section besides those with the codes 48780-1 and 51945-4.	<p>With the exception of bulk ingredient and medical gas product SPL documents, include each section of the content of labeling (package insert or drug facts) in each appropriate SPL content of labeling section.</p> <p>Use the appropriate section header for each section. Add a section GUID, title, etc...</p> <p>This means that all other drug products should have a content of labeling sections.</p> <p>DO NOT include an image of the content of labeling. Enter the text or table from the package insert or drug facts in the appropriate sections SPL content of labeling.</p>
If the code is C73603 or C73604, then the id root must be 2.16.840.1.113883.3.149	<p>If the marketing category is OTC monograph final or OTC monograph not final, then choose “Regulatory Citation” as the “Application or citation number code system.”</p> <p>Include a monograph citation number using the correct format (e.g. “part352”)</p> <p>OTC citations are in the otcval.xml file located in the Additional Validation Files located on this web page:</p> <p>http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm</p>
If the code is C73583, C73584, C73585, C73588, C73593, C73594, C73605,	If the marketing category is ANADA, ANDA, BLA, Conditional NADA, NADA, NDA, NDA authorized generic, Exempt device, Humanitarian Device Exemption, IND,

Content of Labeling & Listing SPL Documents

You have the right section if you have received errors in your content of labeling/listing SPL document.

Error Message	Solution
C75302, C80438, C80440, C80441, or C80442, then the id root is 2.16.840.1.113883.3.150.	Premarket Application, or Premarket Notification, then choose “Application” as the “Application or citation number code system.” Enter a six-digit application number preceded by the marketing category prefix (e.g. NDA013444)
If the code is not C73583, C73584, C73585, C73588, C73593, C73594, C73603, C73604, C73605, C75302, C80438, C80440, C80441 or C80442 then there is no id.	If the marketing category is bulk ingredient, medical gas, export only, unapproved drug other, unapproved homeopathic, or unapproved medical gas DO NOT enter an application number and DO NOT include an “application or citation number code system.”
If the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C), then the marketing category is: C73583 (ANADA), C73588 (Conditional NADA), C73593 (NADA), C73614 (unapproved homeopathic) or C73627 (unapproved drug other).	If the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B or VFD type C, then the marketing category is: ANADA, Conditional NADA, NADA, unapproved homeopathic or unapproved drug other.

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
If the marketing category is C73583 (ANADA), C73588 (Conditional NADA), C73593 (NADA), then the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C)	If the marketing category is ANADA, Conditional NADA, NADA, then the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B or VFD type C
If the marketing category is C73626 (bulk ingredient), then the document type is 53409-9 (bulk ingredient)	If the marketing category is bulk ingredient, then the document type is bulk ingredient
If the document type is 53409-9 (bulk ingredient), then the marketing category is C73626	If the document type is bulk ingredient, then the marketing category is bulk ingredient
Invalid content was found starting with element 'ingredient'. One of '{"urn:hl7-org:v3":asContent, "urn:hl7-org:v3":asPartOfAssembly, "urn:hl7-org:v3":part, "urn:hl7-org:v3":instanceOfKind}' is expected.	<p>Delete all of the packaging description information and enter again.</p> <p>To avoid this error, enter all ingredient information and then add package description</p>
Invalid content was found starting with element 'asEquivalentEntity'. One of '{"urn:hl7-org:v3":asContent, "urn:hl7-org:v3":asPartOfAssembly, "urn:hl7-org:v3":part, "urn:hl7-org:v3":instanceOfKind}' is expected.	<p>There is a problem with the source NDC Product Code.</p> <p>Delete the NDC Source Code from the file.</p> <p>Ensure that are using an up to date version of the listing SPL Xforms. If using version 1.02 or older then download a later version and create a completely new SPL document.</p>

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
Invalid content was found starting with element 'effectiveTime'. One of '{ "urn:hl7-org:v3":component }' is expected.	<p>Create a section under content of labeling tab</p> <p>Qualify section from drop-down menu (i.e. Package.Label Principal Display Panel)</p> <p>Create and enter GUID for section (in section ID field)</p> <p>Open “add effective time” field and enter properly formatted data (YYYYMMDD)</p> <p>Open Observation Media fields (“add media”) and complete sections appropriately</p> <p>“Edit” section intended to reference (link to) jpeg image</p> <p>Before referencing image, replace “enter section text here” with appropriate text from label or, if creating a principal display panel section, enter text from principal display panel of carton or container.</p> <p>Ensure that there are no spaces before or after text.</p> <p>Save section and ensure to save document.</p> <p>Repeat above steps for all sections in which images will be referenced.</p>
There must not be empty or incomplete elements except, in certain circumstances, code, state, title, text, and time (an id must have a root, a code must have a code system).	Ensure that there are no empty fields
Remove description of kit package from the parts	Delete the kit package description information from the component level (part) in the product data elements section.
Missing content of labeling	<p>DO NOT submit content of labeling as a jpeg. Add the text, tables and figures from the package insert or drug facts to each appropriate section of the SPL content of labeling.</p> <p>Include the content of labeling</p>

Images	
For issues with referencing images, see details below	
Error Message	Solution
Reference value must be the file name for the image	Ensure that you have referenced the image in the appropriate content of labeling section - If you are using the Pragmatic Data Validator Lite tool, zip the image with the SPL document and upload the zip file. HOWEVER, DO NOT send a zip file to FDA. - Ensure that you have placed the image in the folder that has the SPL document.
All image files associated with the SPL document must be actually referenced from that SPL document.	Ensure that all files included in the folder are referenced in the SPL document.
Remove extra jpg extension	Do not include an extra jpg extension such as “.jpg.jpg” Use one instead “.jpg”
Size of image file is less than 1 MB	Reduce the size of each image file to under one megabyte (MB)

Packaging & Submitting the SPL Document	
One will receive these errors if one does not observe the procedures for packaging an SPL R4 document for the purpose of registering a drug establishment or listing a drug product.	
Error Message	Solution
SPL document not enclosed within a directory (folder). See section five of Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing	Enclose the SPL document in a folder and upload the folder containing the file via the FDA Gateway OC portal. The path name in the Gateway field should end in the folder name, not the SPL file name.

Packaging & Submitting the SPL Document

One will receive these errors if one does not observe the procedures for packaging an SPL R4 document for the purpose of registering a drug establishment or listing a drug product.

Error Message	Solution
<This submission ci1257520697672.5960@lntap02_te.1.zip is incorrectly packaged, it is a ZIP file, not a directory. See section five of Step-by- Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing.	Remove SPL file and, if applicable, image files from the zip file place in a single folder and resubmit via FDA Gateway OC portal.
Multiple SPL files	Include only one SPL document and, if applicable, associated image files per folder.
Extra folder layers	Send the SPL files and, if applicable, associated image files in a single folder.
A submission must contain only the SPL file whose name ends in '.xml' and associated image files whose names end in 'jpg'.	The file extension of the SPL document should be “.xml” (lower case letters only) The file extension of the JPEG image files should be “.jpg” (lower case letters only) DO NOT insert PDF, Excel or Word documents in the folder with the SPL or image files. DO NOT send PDF, Excel, or Word documents to the FDA OC Gateway portal.
Do not send zip files	DO NOT insert zip files in folder with SPL document. DO NOT send SPL document and, if applicable, associated image files in a zip file. You may zip SPL and image file to test submission via Pragmatic Data Validator Lite tool, but unzip submission prior to sending FDA.
Do not send SPL Xforms	Send the SPL documents, not the SPL Xforms used to create SPL document. You should not send any files which have this file extension: “xhtml” SPL documents have this file extension: “xml”
Do not send short cut file	Do not send the short cut file, send the actual file.

SPL Schema Errors	
The SPL documents must conform to the SPL schema. Basic schema-related errors are listed below.	
Error Message	Solution
There must not be empty or incomplete elements except, in certain circumstances, code, title, text, and time (an id must have a root, a code must have a code system).	Ensure that you have completed the appropriate fields
The value " of attribute 'code' on element 'formCode' is not valid with respect to its type, 'cs'.	Ensure that you have completed the appropriate fields
Value " with length = '0' is not facet-valid with respect to minLength '1' for type 'st'.	Ensure that you have completed the appropriate fields
The value " of attribute 'displayName' on element 'formCode' is not valid with respect to its type, 'st'.	Ensure that you have completed the appropriate fields